To FDA, DEPARTMENT OF HEALTH AND HUMAN SERVICES
Ref.: Docket No. 2006N-0292 Unique Device Identification; Request for Comments

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Comments to Docket No. 2006N-0292

Unique Device Identification is one of the key elements of tracking & tracing concepts for quality control and international agreements for developing safe processes (MEDDEV, etc.). Tools for full filling international requirements for uniqueness of items are developed by national bodies in the early 80th but lifted to international standardization under ISO & ISO/IEC 15459.
UPN and the DOD "UID" strategies fit under this standardization process based on best practices during the last 20 years. HIBC, UCC/EAN and other solutions set the base for the to day's situation.
Where in our area HIBC full fills all of our requirements by means of the latest updates, we would suggest to consider HIBC with a high priority within your UDI considerations.

1) HIBC meets the requirements of alpha numeric product codes and serialized products as well.
2) HIBC has got the appendix "UIM" for Unique Marking of smallest medical products, joined by DIN in Germany, publishing it under DIN V66401 Unique Identification Mark for small products. The UIM solution is shared with other industries such as Precision Mechanics & Optics, Electronic Industry, etc. Related UIM papers for the UID concept of FDA:
   1.1) The World Wide Unique Identification Mark (UIM) for Medical Devices, HIBC UIM 2002-12-20
   1.2) Unique Identification Mark (UIM), DIN V66401, 2005-06

3) ISO 22742 with ASC, EAN/UCC, HIBC
Since the common data structures for marking products uniquely are included with the ISO TC 122 developed ISO 22742 standard "Packaging – linear and two-dimensional symbols for product packaging"
it is well prepared as FDA references for UDI's. It includes the 3 data structures relevant for unique marking, the ASC Data Identifiers, GS1 Application Identifiers and the HIBC structure.

4) RFID
Still RFID has not yet got a key role in our Health Care sector. Nevertheless it is well recommended to address it in time. ISO/IEC developed the global standards for RFID and its cross country applications by taking the requirements from US, Europe, Asia, etc.
Early the HIBC TC in JWG with us developed a guideline targeting to interoperability between existing Barcode and 2D standards and its applications. It includes the required UID features of Barcode applications, but even more, it supplies interoperability between the technologies, so we would recommended to refer to it within the FDA papers as well.

Sources:
HIBC Guidelines and UIM – www.fide-online.org/regulatory_affairs.htm#5
HIBC ISO powered RFID Tag - www.hibc.de
DIN V66401 - www.din.de
ISO 22742 - ISO or National Standards Institutes

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